CURAE- levonorgestrel tablet Curae Pharma360 Inc.

Curae™

Drug Facts

Active ingredient

Levonorgestrel 1.5 mg

Purpose

Emergency contraceptive

Use

for women to reduce chance of pregnancy after unprotected sex (if a contraceptive failed or if you did not use birth control)

Warnings

Allergy alert

Do not use if you have ever had an allergic reaction to levonorgestrel

Sexually transmitted diseases (STDs) alert

This product does **not** protect against HIV/AIDS or other STDs

Do not use

- if you are already pregnant (because it will not work)
- for regular birth control

Ask a doctor or pharmacist before use if you are taking efavirenz (HIV medication) or rifampin (tuberculosis treatment) or medication for seizures (epilepsy). These medications may reduce the effectiveness of levonorgestrel.

When using this product you may have

- menstrual changes
- tiredness
- breast pain
- dizziness
- lower stomach (abdominal) pain
- headache
- vomiting
- nausea

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control center right away 1-800-222-1222

Directions

- take as soon as possible within 72 hours (3 days) after unprotected sex. The sooner you take it, the better it will work.
- If you vomit within 2 hours of taking the medication, call a healthcare professional to find out if you should repeat the dose

Other information

- read the instructions, warnings, and enclosed product leaflet before use
- do not use if carton is open or blister seal is broken or missing
- store at 20° to 25°C (68° to 77°F)

Inactive ingredients

colloidal silicon dioxide, FD&C Yellow No.6 aluminum lake, lactose monohydrate, magnesium stearate, and pregelatinized starch

Questions or comments?

Call 1-888-885-3054 Monday - Friday 9 AM - 5 PM EST

Manufactured for: Curae Pharma360 Inc. San Francisco, CA 94105 NDC 73358-241-01 Product made in Germany Issued: March 2023

PRINCIPAL DISPLAY PANEL - 1.5 mg Tablet Blister Pack Carton

NDC 73358-241-01

Curae™

Levonorgestrel Tablet 1.5 mg

EMERGENCY CONTRACEPTIVE

REDUCES CHANCE OF PREGNANCY AFTER UNPROTECTED SEX

NOT FOR REGULAR BIRTH CONTROL

- The sooner you take it, the more effective it will be
- Take as soon as possible within 72 hours (3 days) after unprotected sex
- Will not harm an existing pregnancy



CURAE

levonorgestrel tablet

	Information	

Product Type HUMAN OTC DRUG Item Code (Source) NDC:73358-241

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Levonorgestrel (UNII: 5W7SIA7Y7W) (Levonorgestrel - UNII:5W7SIA7Y7W)	Levonorgestrel	1.5 mg

Levonorgestrei (UNII: 5W/SIA/YZW) (Levonorgestrei - UNII:5W/SIA/YZW) Levonorgestrei 1.5 mg

Inactive Ingredients

Ingredient Name	Strength
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Lactose Monohydrate (UNII: EWQ57Q8I5X)	
Starch, Corn (UNII: O8232NY3SJ)	
Magnesium Stearate (UNII: 70097M6I30)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Fd&C Yellow No. 6 (UNII: H77VEI93A8)	

Product Characteristics			
Color	ORANGE (Light peach)	Score	no score
Shape	ROUND (convex)	Size	8mm
Flavor		Imprint Code	17
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:73358-241- 01	1 in 1 CARTON	03/01/2023		
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202380	03/01/2023	

Labeler - Curae Pharma360 Inc. (080719852)

Registrant - Naari Pte. Limited (659345996)

Revised: 3/2023 Curae Pharma360 Inc.